



USDA Foreign Agricultural Service

# GAIN Report

Global Agriculture Information Network

Template Version 2.09

Voluntary Report - public distribution

**Date:** 8/25/2006

**GAIN Report Number:** E36116

## EU-25

### FAIRS Product Specific

## EU Proposal: Composition & Labeling of Infant & Follow-on Formulae

## 2006

**Approved by:**

Stan Cohen

U.S. Mission to the EU

**Prepared by:**

Hilde Brans

---

**Report Highlights:**

Third countries have until October 7, 2006, to comment on the EU's proposal to amend the provisions on the essential composition and labeling of infant formulae and follow-on formulae. Certain provisions on pesticides are also being revised.

---

Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Brussels USEU [BE2]  
[E3]

## EU Proposal: Composition and Labeling of Infant Formulae and Follow-on Formulae

### Notification

On August 8, 2006, the EU notified to the WTO its proposal to amend the provisions on the essential composition and labeling of infant formulae and follow-on formulae. The proposal amends the current definitions, taking into account the latest scientific advice on the essential composition of the products concerned. Certain provisions on labeling and pesticide residues are also being revised. Third countries have 60 days, until October 7, to comment on the proposed rules.

The text of the proposal, notified to the WTO as G/TBT/N/EEC/115, can be downloaded from DG Enterprise's TBT webpage at <http://ec.europa.eu/enterprise/tbt/index.cfm?fuseaction=Search.viewMailingDetail&CountryId=EEC&num=115&dspLang=EN>. An overview of EU measures notified to the WTO is available on our website at <http://useu.usmission.gov/agri/WTOnotif.html>.

### Proposal

[Commission Directive 91/321/EEC](#) on infant formulae and follow-on formulae has been substantially amended several times. The proposed new directive would bring the basic act and all its amendments into one legislative act. Only products complying with the provisions set out in this directive may be marketed as infant formulae and follow-on formulae within the EU. Operators must forward a copy of the product label to the competent authority of the member state where they want to market the product.

Point 2 of Annex I and Annex II to the proposed directive defines the essential composition of: formulae manufactured from cows' milk proteins, formulae manufactured from protein hydrolysates, formulae manufactured from soy protein isolates, alone or in a mixture with cows' milk protein. Infant formulae and follow-on formulae must be manufactured from protein sources defined in those annexes. Other food ingredients may be used if their suitability for particular nutritional use has been established by scientific data. Specific rules for preparations based wholly or partly on other sources of protein will be adopted at a later date.

Annex III lists the mineral substances, vitamins, amino acids and other nitrogen compounds, and other substances having a particular nutritional purpose, which may be used in the manufacture of infant formulae and follow-on formulae.

### Pesticides

As a general rule, infant formulae and follow-on formulae may not contain residues of individual pesticides at levels exceeding 0.01 mg/kg, which is in practice the minimum detectable level. Pesticides listed in Annex VIII are prohibited in the manufacture of infant formulae and follow-on formulae. Residues of pesticides listed in Annex IX may not exceed the specified maximum levels. The maximum residue levels apply to products ready for consumption.

### Labeling

Article 13 of the proposal sets out specific labeling requirements for infant formulae and follow-on formulae in addition to those established by the [general labeling directive 2000/13/EC](#). Product labels must enable consumers to make a clear distinction between

infant formulae and follow-on formulae. In order not to discourage breast-feeding, the use of the terms "humanized", "maternalized", "adapted" or similar terms is prohibited.

Mandatory particulars include: statements indicating that the product is only suitable for particular nutritional use by either infants from birth when they are not breast-fed or by infants over the age of six months, the available energy value expressed in kJ and kcal, the average quantity of mineral substances and vitamins expressed in numerical form per 100 ml, instructions for preparation and storage.

Labels on infant formulae must also bear a statement concerning the superiority of breast-feeding and a statement that the product should only be used on the advice of qualified persons. These statements must be preceded by the words "Important Notice" or their equivalent. Annex IV to the proposed directive specifies in which cases infant formulae labels may bear nutrition and health claims and sets out the conditions. Pictures of infants are prohibited on infant formulae labels.

**Visit our website:** our website <http://useu.usmission.gov/agri/> provides a broad range of useful information on EU import rules and food laws and allows easy access to USEU reports, trade information and other practical information. More information on food for particular nutritional uses can be found at <http://useu.usmission.gov/agri/partnutr.html>. E-mail: AgUSEUBrussels@usda.gov

**Related report(s) from USEU Brussels:**

Report Number	Title	Date Released
E35051	<a href="#">Revision of the EU's Infant Formulae and Follow-on Formulae Directive</a>	3/14/2005
These report(s) can be accessed through our website <a href="http://useu.usmission.gov/agri">http://useu.usmission.gov/agri</a> or through the FAS website <a href="http://www.fas.usda.gov/scripts/attacherep/default.asp">http://www.fas.usda.gov/scripts/attacherep/default.asp</a> .		